PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1040581 PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/008486	International filing date *(day/month/year)* 29.07.2004	Priority date *(day/month/year)* 07.08.2003
International Patent Classification (IPC) or national classification and IPC A61B10/00		
Applicant TESSITORE Marco et Al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 11 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.06.2005	10.11.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Mayer-Martenson, E Telephone No. +31 70 340-4401

Form PCT/IPEA/409 (Cover Sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/008486

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-4	as originally filed
5-11	filed with telefax on 13.07.2005

Claims, Numbers

1-9	filed with telefax on 13.07.2005

Drawings, Sheets

2/5, 4/5	as originally filed
1/5, 3/5, 5/5	filed with telefax on 13.07.2005

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US-A-3 683 892 (HARRIS ROY M) 15 August 1972 (1972-08-15)

The document D1 is regarded as being the closest prior art to the subject-matter of claim , and shows (the references in parentheses applying to this document):

a device for taking a sample of biological tissue transcutaneously, comprising: needle means (1) *comprising a tubular body, having an end associable with a grip and being provided with an edge* (2) *free at the opposite end, lamina means* (3) *protruding towards said proximal end and moveable between a neutral position in which said lamina means lies near said tubular body and an operating position in which said lamina means is distanced from said tubular body* (cf. fig.1)

The subject-matter of claim 1 differs from this known device in that the lamina means is formed from a portion of said tubular body;

The problem to be solved by the present invention may be regarded as minimizing trauma to a patient by a reduced needle diameter;

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
in D1 the needle needs to have sufficient thickness to incorporate shaft 6. This requires a thick needle wall which increases the aperture necessary to extract a tissue sample from the body. By forming the lamina from the needle wall the hinge and consequently the needle wall can be made very thin which reduces patient trauma.
Neither in D1 nor in any other document cited a hint can be found to the above solution of the problem. Therefore the subject matter of claim 1 is considered inventive.

Claims 2-9 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

According to
~~In a first aspect of~~ the invention, a device is provided for taking a sample of biological tissue transcutaneously, comprising: needle means having a tubular-shaped body, having an end associable with a grip and being provided with an edge free at the opposite end, lamina means movable between a neutral position wherein it lies near said tubular-shaped body and an operating position wherein it is distanced from the latter, characterized in that said lamina means protrudes towards said end.

Owing to ~~this aspect of~~ the invention, it is possible to create a biopsy device in rather a simple manner because the lamina means can be an integral part of the needle means.

Furthermore, to actuate the lamina means it is sufficient to extract the device from the body of the patient subjected to biopsy. In fact, since the lamina means points towards the grip of the device, it tends during extraction of the latter to engage automatically in the sample, cutting a root portion thereof.

~~In a second aspect of the invention, a device is provided for~~ taking a sample from a biological tissue transcutaneously, comprising: needle means having a tubular-shaped body, provided with an end associable with a grip and with an edge free at the opposite end, characterized in that said needle means comprises window means shaped in such a way that said sample can be extracted by said device through said window means.

Owing to this aspect of the invention, to extract the sample from the device it is sufficient to remove the sample through ~~the above window means without having to use the probe.~~

The invention may be better understood and implemented with reference to the enclosed drawings, which illustrate an embodiment by way of non-limiting example in which:

Figure 1 is an enlarged and fragmentary perspective view of the components of a device according to the invention;

Figure 2 is an enlarged fragmentary and partially sectioned perspective view, showing the device in Figure 1 assembled;
Figure 3 is an enlarged and fragmentary perspective view of one of the components of the device in Figure 1;
Figure 4 is an enlarged and fragmentary longitudinal section of the device in Figure 1, shown in an initial operating phase;
Figure 5 is an enlarged and fragmentary longitudinal section of the device in Figure 4, shown in a further operating phase;
Figure 6 is an enlarged and fragmentary longitudinal section of the device in Figure 5, shown in a yet further operating phase;
Figure 7 is an enlarged and fragmentary schematic longitudinal section, of a further embodiment of the device according to the invention shown in an operating phase;
Figure 8 is an enlarged and fragmentary schematic longitudinal section of the device in Figure 7, shown in a further operating phase;
Figure 9 is an enlarged and fragmentary schematic longitudinal section of a further embodiment of the device according to the invention, shown in an operating phase;
Figure 10 is an enlarged and fragmentary schematic longitudinal section, of the device in Figure 9, shown in a further operating phase;
Figure 11 is an enlarged and fragmentary schematic longitudinal section of another yet further embodiment of the device according to the invention.

With reference to figures 1 to 3, a device 1 for conducting bone-marrow biopsies comprises a hollow needle 2 ~~with a cylindrical tubular shape, having~~ <-> a proximal end provided with a known operating grip, which is therefore neither shown or disclosed in detail, and a tapered distal end 5 that is provided with a cutting edge 6.

<-> having an outer tubular body (2a) and

A tubular ~~element~~ body 3, inside which a stem 4 is slidingly insertable is slidingly insertable inside the hollow needle 2 and is arranged to arrest inside itself a sample 25 taken from the patient according to a manner that will be disclosed in greater detail below. The tubular ~~element~~ body 3 comprises a cylindrical wall 8 delimiting a tubular cavity 10 interposed between a further proximal end that is not shown, provided with an operating grip of the known type, which is not shown, and further distal end 7 provided with a circular edge 12. The cylindrical wall 8, near the further distal end 7, is provided with a release window 13, arranged to allow the extraction of the sample 25 at the end of the biopsy. The release window 13 is delimited by a pair of straight borders 14, an arched proximal border 15 and an arched distal border 16. The straight borders 14 are parallel to one another and to a longitudinal axis of the tubular ~~element~~ body 3 and are connected with the arched proximal border 15 and with the arched distal border 16. The arched proximal border 15 is tilted towards the further proximal end of the tubular ~~element~~ body 3, such as to delimit with the straight borders 14 a pair of equal obtuse angles, which are not shown. The arched distal border 16 is tilted in the direction of the further distal end 7, such as to form with the straight borders 14 a pair of equal obtuse angles that are not shown, the obtuse angles having the same degree as the degree of the obtuse angles formed by the arched proximal border 15 with the straight borders 14. A further embodiment of the tubular ~~element~~ body 3 is also provided that is not shown that is made without the release window 13. In the cylindrical wall 8, between the release window 13 and the further distal end 7, three V-shaped notches 9 are obtained with the apex pointing towards the further proximal end of the tubular ~~element~~ body 3. The notches 9 are arranged in such a way that the apices of the V are angularly spaced between themselves by about 120°. At each notch 9 a triangular lamina,

or appendage, 11 is defined by a portion of cylindrical wall 8 that is near the notch 9 and points to the further proximal end of the tubular body element 3. Each lamina 11 has a free cutting border 23 and a constrained border 24, indicated by a broken line, which is straight and integral with the remaining cylindrical wall 8. Each lamina 11 is furthermore slightly bent towards a longitudinal axis of the tubular body element 3, in such a way as to protrude, if there is no opposing movement, inside the tubular cavity 10, as indicated by the broken lines in Figure 3.

The prior-art stem 4 comprises a cylindrical rod 17 made with a transverse section such as to enable it to slide inside the tubular cavity 10. The rod is interposed between a yet further proximal end that is not shown provided with an operating grip that is not shown and a yet further distal end 18 comprising a penetration point 19. The length of the stem 4 is greater than the length of the tubular body element 3 and of the hollow needle 2, so that the penetration point 19 protrudes outside the distal end 5 when the device 1 is assembled.

Figure 11 shows a yet further embodiment of the device 1 that does not comprise the tubular body element 3, since the laminae 11 are obtained directly in the wall of the hollow needle 2.

With reference to Figures 4, 5 and 6, when the device 1 is assembled for use, inside the hollow needle 2 the tubular body element 3 is positioned and inside the latter the stem 4 is located, with the penetration point 19 protruding from the distal end 5. During this phase, the rod 17 compresses the laminae 11, preventing the latter from protruding inside the tubular cavity 10. To perform a bone-marrow biopsy on a patient, an operator, after positioning the device 1 assembled near the anatomical region housing a preselected bone formation, for example the iliac crest, makes the hollow needle 2 penetrate the underlying tissues in a penetration direction F1. As shown in Figure 4, where for the sake of

simplicity the layers of skin and muscular tissue have been omitted, when the hollow needle 2 gets near a bone 20, the penetration point 19 is used by the operator to perforate a surface layer of particularly resistant compact bone tissue 21. The stem 4 is then removed and the hollow needle 2 containing the tubular body 3 is pushed deeper into the bone 20 so as to reach an underlying spongy bone tissue 22. The latter tends to penetrate inside the tubular cavity 10 as the hollow needle 2 continues to progress into the bone 20, thereby causing the formation of the approximately cylindrical sample 25, which remains connected to the surrounding spongy bone tissue 22 only near its distal end or root 26.

During penetration of the device 1 into the spongy bone tissue 22, the laminae 11, which are no longer compressed by the rod 17, protrude slightly inside the tubular cavity 10 and are turned in a direction F2 opposite the penetration direction F1. In this way, the laminae 11 cannot be hindered and/or damaged by particularly hard tissues constituting the sample 25 inasmuch as the hard tissues will cause retraction of the laminae 11 into the thickness of the cylindrical wall 8. Furthermore, for the same reason, it is not even possible for the laminae 11 to damage the tissue forming the sample 25.

When the desired sample depth has been reached, the operator can proceed to extract the device 1 by acting in direction F2 opposite the penetration direction F1. To remove the sample 25 from the surrounding tissue 22, it is not necessary to perform any dislocating movement. In fact, by simply extracting the hollow needle 2 and the coaxial tubular body 3 in the direction F2, the laminae 11, thanks to their initial tilt, progressively engage with the sample 25. The latter presses on the laminae 11, which bend and approach one another near the longitudinal axis of the tubular body 3, tending to close the tubular cavity 10. It is therefore sufficient for the operator to rotate only slightly the device 1 around the

longitudinal axis of the latter for the free cutting borders 23 of the laminae 11 to separate the root 26 of the sample 25 from the surrounding spongy bone tissue 22. The laminae 11, in their folded position, hold the sample 25 in the tubular cavity 10.

Once the sample 25 has been held in the tubular cavity 10, the operator can first remove the device 1 from the body of the patient and then the tubular ~~element~~ body 3 from the proximal end of the hollow needle 2 in such a way as to recover the sample 25 via the release window 13. In this way, the sample is extracted from the device 1 without recourse to further instrumental procedures, i.e. the operator is not obliged to slide a probe inside the tubular ~~element~~ body 3 until the ejection of the sample 25 is obtained.

Further embodiments of the device 1 are furthermore provided that enable the latter to be used effectively to perform a transcutaneous biopsy of soft tissues. The latter are in fact not sufficiently consistent to induce flexure of the laminae 11 during extraction of the device 1 from the body of the patient, as previously disclosed with reference to the biopsy of hard tissue. As a result, the free cutting borders 23 of the laminae 11 are unable to cut the root 26 of the sample 25, which cannot therefore be removed.

With reference to Figures 7 and 8, an ~~further~~ inner tubular ~~element~~ body 27, fashioned in the shape of a hollow cylinder that is slidingly insertable inside the tubular ~~element~~ body 3, is positioned in the latter in such a way that one of its distal closing ends 28 is at a certain distance from the laminae 11. The tubular ~~element~~ body 3, which in this embodiment is provided with a distal end, which is not shown and has for example the shape of an oblique cut, can in turn be inserted into the hollow needle 2 (not shown for the sake of simplicity in Figures 7 to 10). The device 1 is made to penetrate into the body of a patient by an operator until it reaches a desired

depth, in such a way as to cause the formation of a sample of soft tissue, not shown, which remains contained inside the apparatus 1. At this point, the operator slides the ~~further~~ inner tubular element 27 inside the tubular element body 3 in direction F1 indicated by the arrow so that the closing end 28 engages with the laminae 11 bending them towards a longitudinal axis of the device 1. The laminae 11, by flexing, resect the root of the sample, which is not shown, isolating the latter from the surrounding tissue, which is not shown. The sample thus remains enclosed inside the device 1, and can thus be easily extracted together with the latter from the body of the patient.

In another embodiment shown in Figures 9 and 10, as an alternative to the ~~further~~ inner tubular ~~element~~ body 27, an ~~yet further~~ outer tubular body 29 is provided that is shaped in such a way as to be slidingly interposable between the hollow needle 2 and the tubular ~~element~~ body 3. The ~~yet further~~ outer tubular body 29 distally comprises three protuberances 30 reciprocally angularly spaced by approximately 120° and having their convexity turned towards the cylindrical wall 8 of the tubular element body 3. Owing to a longitudinal incision 31 obtained in the wall of the yet further tubular body 29, the latter can be forced against the cylindrical wall 8. In this way, by positioning the ~~yet further~~ outer tubular ~~element~~ body ~~30~~ 29 at a certain distance from the notches 9, each protuberance 30 is applied outside the cylindrical wall 8. In use, after a sample of tissue, which is not shown, has been enclosed inside the device 1, the operator slides the ~~yet further~~ outer tubular body 29 in the direction F1 indicated by the arrow. In this way the protuberances 30 engage with the laminae 11, flexing them and the free cutting borders 23 of the latter resect the root that is not shown of the tissue sample. The latter, separated by the surrounding tissue, remains enclosed within the device 1 and can be removed together with the latter from the body of the patient.

CLAIMS

1. Device (1) for taking a sample (25) of biological tissue (22) transcutaneously, comprising: needle means (2) comprising a tubular body (3), having a proximal end associable with a grip and being provided with an edge (6) free at the opposite end (5), lamina means (11) protruding towards said proximal end and movable between a neutral position in which said lamina means (11) lies near said tubular body (3) and an operating position in which said lamina means (11) is distanced from said tubular body (3), characterized in that said lamina means (11) is formed from a portion (8) of said tubular body (3).
2. Device according to claim 1, wherein said needle means (2) furthermore comprises window means (13), shaped to enable said sample (25) to be extracted by said device (1).
3. Device according to claim 1, or 2, wherein said needle means (2) comprises an outer tubular body (2a; 29) extending externally of said tubular body (3).
4. Device according to claim 3, wherein said outer tubular body (29) comprises protuberances (30) so shaped as to move said lamina means (11) from said neutral position to said operating position.
5. Device according to claims 1, or 2, and further comprising an inner tubular body (27) slidably insertable inside said tubular body (3).
6. Device according to any preceding claim, wherein said lamina means (11) is triangle-shaped.
7. Device according to any preceding claim, wherein said lamina means (11) are angularly spaced between one another by about 120°.
8. Device according to any preceding claim, wherein said lamina means (11) is defined by notches (9) that are obtained in said tubular body (3).
9. Device according to any preceding claim, wherein said window means (13) has a perimeter defined by a pair of straight margins (14) that are connected at a pair of ends by an arched proximal border (15) and at a pair of opposite ends by an arched distal border (16).

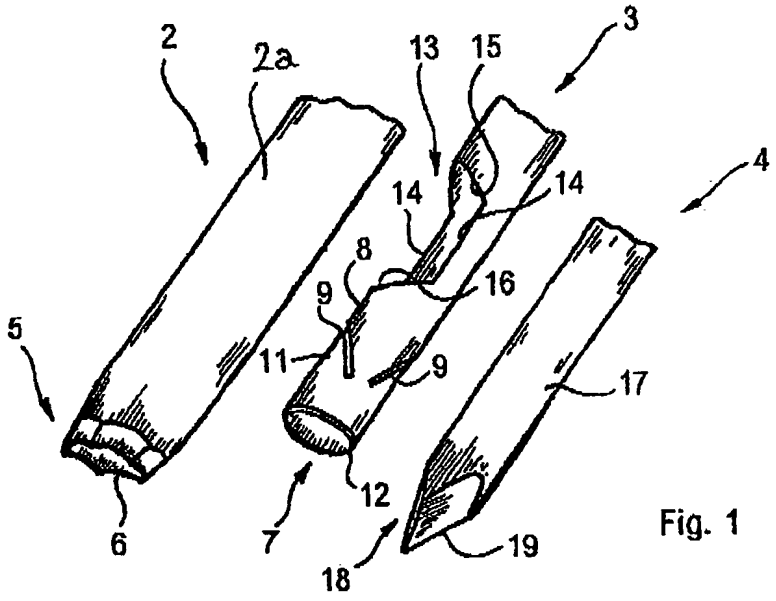

Fig. 1

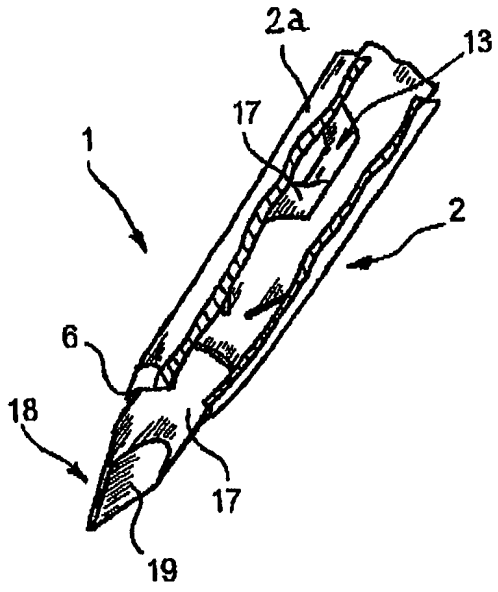

Fig. 2

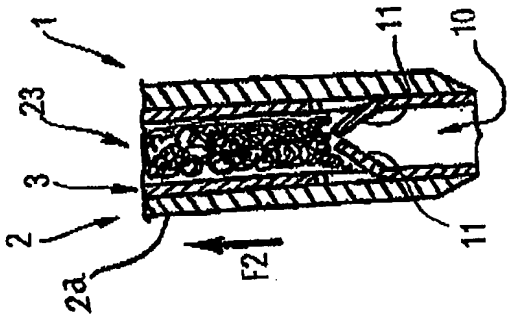

Fig. 6

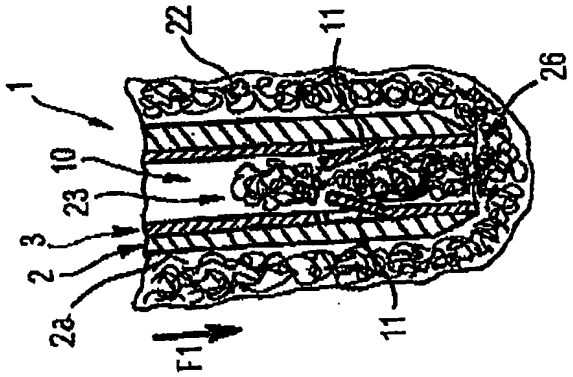

Fig. 5

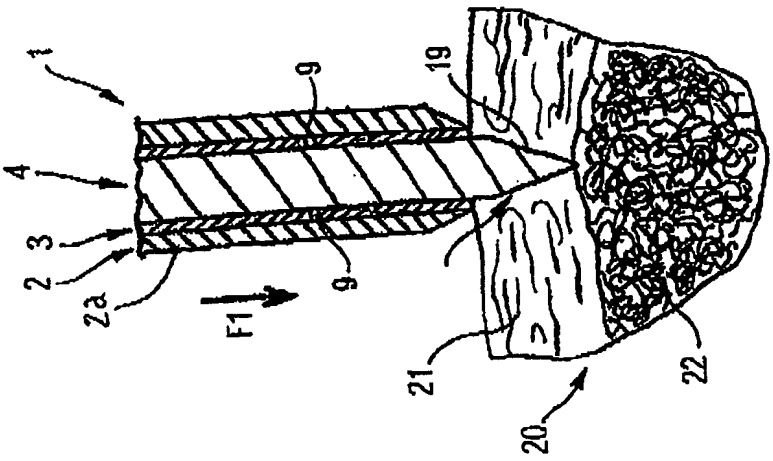

Fig. 4

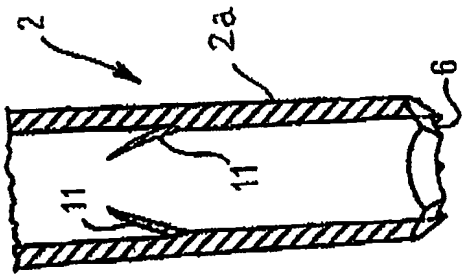

Fig. 11

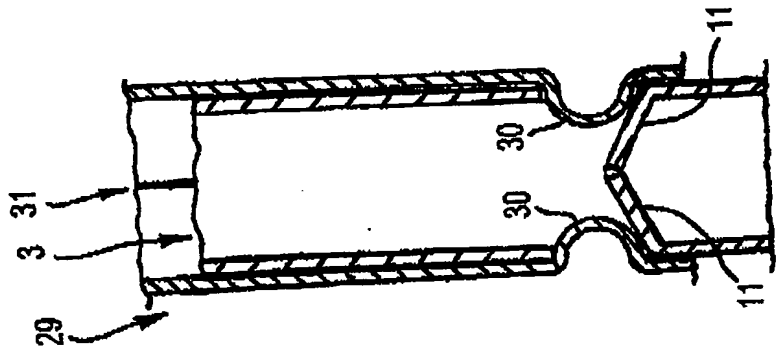

Fig. 10

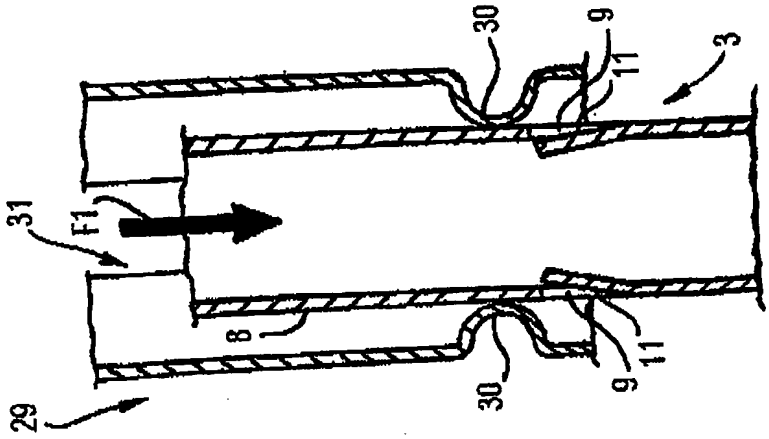

Fig. 9